Assurances

Domestic Assurances

For a domestic institution that does not have an assurance, the HSO will notify the CDC investigator that the collaborating institution(s) will need to obtain a single project assurance (SPA). The HSO will prepare the respective SPA(s). Once the CDC investigator has obtained all necessary signatures, the assurance will be returned to the HSO and subsequently forwarded to OPRR for approval. For an independent investigator not affiliated with an institution, completion of an Agreement for an Independent Investigator (AII) is required.

***Procedure for CDC Investigators Completing a Domestic SPA Document*:**

1. The CDC investigator will be given an electronic copy of the SPA specific for the institution/protocol in which the research project is being conducted.

2. The first page of the SPA must be typed on appropriate collaborating institutional letterhead.

3. It is the responsibility of the investigator to secure the following signatures:
   (a) If the institution has its own IRB, the assurance must be signed and dated in four places:

      (1) Signature I, authorized official of the institution providing the assurance

      (2) Signature III, IRB chairperson.

      (3) Signature IV, responsible project investigator. This is the coinvestigator at the collaborating institution, the same individual named in Part 2 (I) and Part 3.

      4. The IRB chairperson must also sign the IRB roster, which is attachment "A" of the SPA.

   (b) If the institution does not have its own IRB, it must rely on the IRB of another institution, preferably one in the geographic area in which the study is to be conducted. The designated IRB MUST be affiliated with an

(2) Signature II, authorized official of the institution with the IRB

(3) Signature III, IRB chairperson.

(4) Signature IV, responsible project investigator. This is the coinvestigator at the collaborating institution, the same individual named in Part 2 (I) and Part 3.

5. The IRB chairperson must also sign the IRB roster, which is attachment "A" of the SPA.

(c) Under some circumstances, it may not be possible to rely on the IRB in the geographic area in which the study is to be conducted. In this case, the institution may request that the CDC IRB serve as the IRB of record; however, a local representative from the community in which the study is to be conducted is required to sit on the IRB for review of that protocol. The assurance must be signed and dated in two places:

(1) Signature I, authorized official of the institution providing the assurance

(2) Signature IV, responsible project investigator. This is your coinvestigator at the collaborating institution, the same individual whom you named in Part 2 (I) and Part 3.

In the above three scenarios, CDC's Human Subjects Office will obtain all remaining signatures.:

Signature Notes: The authorized official signing in signature block I must be someone at the institution who can "bind" the institution to the agreement (i.e., the SPA). Further, THE AUTHORIZED OFFICIAL (SIGNATURE "I") AND THE IRB CHAIRPERSON MAY NOT BE THE SAME INDIVIDUAL DUE TO THE APPEARANCE OF A CONFLICT OF INTEREST. The constitution of the IRB is defined in 45 CFR 46, Section 107 a-f. Specifically, the IRB is to have at least five members, with varying backgrounds; will not consists entirely of men or entirely of women nor consist entirely of members of one profession; shall include at least one scientist and one nonscientist; and shall include at least one member who is not otherwise affiliated with the institution.

The SPA must not be signed by ANYONE until the protocol is approved by the collaborating IRB. The paragraph immediately above the signature blocks reads: "The officials signing below assure that the project referenced above was approved by the IRB of the date indicated and the project will be conducted in accordance with the requirement of Part 46, Title 45 of the Code of Federal Regulations and this Assurance document. A dated roster listing the current membership of the designated IRB is attached."

4. The collaborating institution's IRB-approved protocol must be sent along with the SPA document.

5. Return the signed SPA document and protocol to the following address:

Virginia Talley
CDC Mailstop D50
1600 Clifton Rd., NE
Atlanta, GA 30333
(404) 639-7249 (404) 639-7341 (FAX)

6. The HSO will check the documents for completeness and forward them to OPRR for approval. OPRR will then review both the SPA and the protocol/consent forms, etc., and, if all is in order, issue a SPA number.

(In an emergency, a signed facsimile may be sent while the original is in transit.)

7. Once approved and given a number, OPRR will send one signed original to CDC's HSO and one to the collaborating institution.

Procedure for CDC Investigators Completing a Domestic AII Document:

The agreement for an Independent Investigator is for use by investigators who are participating in an HHS-conducted or supported research project when acting in their own name independent of any hospital, clinic, or other facility. An agreement is not required for referral physicians or other physicians to whom research subjects are returned by an investigator who maintains responsibility for management of subjects.

1. The CDC investigator will be given an electronic copy of the AII specific for the collaborator with whom the research project is being conducted.

2. The first page of the AII must be typed on appropriate independent investigator letterhead.

3. It is the responsibility of the CDC investigator to secure the signature of the collaborating independent investigator (D1.(b)) when CDC has been designated the IRB of record.

4. the signed SPA document and protocol to the following address:

Virginia Talley
CDC Mailstop D50
1600 Clifton Rd., NE
Atlanta, GA 30333
(404) 639-7249 (404) 639-7341 (FAX)

5. After CDC's IRB approves the protocol, the HSO will check the AII for completeness and forward the AII to OPRR for approval. OPRR will review AII and the protocol/consent forms, etc., and, if all is in order, issue an AII number.

(In an emergency, a signed facsimile may be sent while the original is in transit.)

6. Once approved and given a number, OPRR will send one signed original to CDC's HSO and one to the collaborating investigator.

International Single and Cooperative Project Assurances

The CDC investigator should explain to his/her colleagues at the host country institution(s) with whom he/she will be conducting the research, the need for CDC and host country review of the protocol. Also, the need for and requirements of an assurance are discussed and agreed upon. The CDC investigator subsequently provides a packet of assurance material to each collaborating host country institution. The host country institution then convenes the appropriate EC or, in the case of a SPA, may decide to rely on another EC.

Procedure for Obtaining an International Single Project Assurance (SPA):

1. The CDC investigator will be given an electronic copy of the SPA specific for the institution/protocol in which the research project is being conducted.

2. The SPA must be in English; OPRR only accepts and approves English versions. However, OPRR will sign a foreign translation when accompanied by the English version (both documents must have original signatures). Thus, the CDC investigator may need to have the assurance translated into the official language of the host country if the host country so wishes. FYI, the HSO provides French and Spanish translations.

3. The first page of the SPA must be typed on appropriate host country institutional letterhead. If letterhead is not available, an official stamp or seal may be used at each signature.

4. It is the responsibility of the CDC investigator to secure the following dates and signatures:

    (a) If the institution has its own EC, the assurance must be signed and dated in four places:

        (1) Signature I, authorized official of the institution providing the assurance

        (2) Signature III, EC chairperson.

(b) If the institution does not have its own EC, it must rely on the EC of another institution, preferably one in the same country/geographic area in which the study is to be conducted. The assurance must be signed and dated in five places:

(1) Signature I, authorized official of the institution providing the assurance

(2) Signature II, authorized official of the institution with the EC

(3) Signature III, EC chairperson.

4. Signature IV, responsible project investigator. This is the host country coinvestigator at the collaborating institution, the same individual named in Part 2 (I) and Part 3.

(5) The EC chairperson must also sign and date the EC roster, which attachment "A" of the SPA.

(c) Under rare circumstances, it may not be possible to rely on an EC in the host country/geographic area in which the study is to be conducted (one may not be in existence). In this case, the institution may elect to request that the CDC EC serve as the EC of record; however, a local representative from the community in which the study is to be conducted is required to sit on the EC for review of the protocol. The assurance must be signed and dated in two places:

(1) Signature I, authorized official of the institution providing the assurance

(2) Signature IV, responsible project investigator. This is the host country coinvestigator at the collaborating institution, the same individual named in Part 2 (I) and Part 3.

In the above three scenarios, CDC's Human Subjects Office will obtain all remaining signatures.

1. Representatives of both genders (at least one female & male).

2. Non-scientist.

3. Non-affiliated voting member (not employed by or belonging to this institution, [i.e., a local community member])

4. Must have at least five voting members, a sufficient number of professionals to review the technical aspects of the project. The EC shall include persons knowledgeable about institutional commitments and regulations, applicable law, and standards of professional conduct and practice. Furthermore, if applicable, the EC shall include one or more individuals who are knowledgeable about and experienced in working with vulnerable categories of subjects, such as children (45 CFR 46, Subpart D), prisoners (45 CFR 46, Subpart C), pregnant women, fetuses, and human **in vitro** fertilization (45 CFR 46, Subpart B), or handicapped or mentally disabled persons.

The SPA must not be signed by ANYONE until the protocol is approved by the designated collaborating EC.

5. The documents should be hand carried or sent by express mail to:

Mrs. Virginia Talley
Assurance Coordinator
CDC Mailstop D50
1600 Clifton Rd., NE
Atlanta, GA 30333
Phone (404) 639-7621 Fax (404) 639-7342

(In an emergency, a signed facsimile may be sent while the original is in transit.)

6. After CDC's IRB approves the protocol, the HSO will ask the CDC investigator to send a final "clean" copy of the EC-approved protocol/consent forms, etc., incorporating all changes. A copy will be sent to OPRR with the signed SPA. OPRR will then review both the SPA and the protocol/consent forms, etc., and, if all is in order, issue a SPA number.

Procedure for Obtaining an International Cooperative Project Assurance (CPA):

Since the CPA is not protocol-specific, the CPA document can be completed months in advance of a protocol coming to the HSO for review and approval by CDC's IRB. The following instructions apply when an investigator anticipates working collaboratively with a foreign institution:

1. The CDC investigator will be given an electronic copy of the CPA specific for the institution in which the research project is being conducted.

2. The CPA must be in English; OPRR only accepts and approves English versions. However, OPRR will sign a foreign translation when accompanied by the English version (both documents must have original signatures). Thus, the CDC investigator may need to have the assurance translated into the official language of the host country if the host country so wishes. FYI, the HSO provides French and Spanish translations.

3. The first page of the CPA must be typed on appropriate host country institutional letterhead. If letterhead is not available, an official stamp or seal may be used at each signature.

4. It is the responsibility of the CDC investigator to secure the following dates and signatures:

    (a) If the institution has its own EC, the assurance must be signed and dated in three places.

        (1) Signature A, authorized official of the institution providing the assurance.

        (2) Signature D, Ethics Committee Chairperson.

        (4) The EC chairperson must also sign and date the EC roster, which is attachment "A" of the CPA.

    (b) If the institution does not have its own EC, it must rely on the EC of another institution in the same country/geographic area in which the study

(3) Signature D, EC chairperson.

(4) The EC chairperson must also sign and date the EC roster, which makes up the last page of the SPA.

In the above scenarios, CDC's Human Subjects Office will obtain all remaining signatures.

Signature Notes: The authorized official signing in signature block A must be someone at the institution who can "bind" the institution to the agreement (i.e., the CA).

A dated roster of EC members must be attached to the assurance. The roster must include the EC chairperson's signature. The ethics committee membership must include the following:

1. Representatives of both genders (at least one female & male).

2. Non-scientist.

3. Non-affiliated voting member (not employed by or belonging to this institution, [i.e., a local community member])

4. Must have at least five voting members, a sufficient number of professionals to review the technical aspects of the project. The EC shall include persons knowledgeable about institutional commitments and regulations, applicable law, and standards of professional conduct and practice. Furthermore, if applicable, the EC shall include one or more individuals who are knowledgeable about and experienced in working with vulnerable categories of subjects, such as children (45 CFR 46, Subpart D), prisoners (45 CFR 46, Subpart C), pregnant women, fetuses, and human **in vitro** fertilization (45 CFR 46, Subpart B), or handicapped or mentally disabled persons.

These documents should be hand carried or sent by express mail to:

Mrs. Virginia Talley
Assurance Coordinator
CDC Mailstop D50
1600 Clifton Rd., NE
Atlanta, GA 30333

original (if applicable) to the CDC investigator, who will the forward to the appropriate host institution official.

Note: Once a protocol is submitted to and reviewed and approved by the CDC IRB, the approved protocol should be submitted to the designated host country institution EC for review and approval. A copy of the host institution's EC report must then be sent to CDC's HSO to become a permanent part of the record.

The International SPA and CPA can also be used for Federally-funded research. When PGO plans to fund a foreign institution, PGO will notify the HSO. The procedures outlined above will apply.